Is transapical aortic valve implantation really less invasive than minimally invasive aortic valve replacement?

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Background: Transcatheter valve implants currently draw their justification for use from reduction of perioperative risk. However, patient age and comorbidities are independent predictors of adverse outcome after aortic valve replacement, regardless of surgical approach. Therefore, it is unclear whether transapical aortic valve implantation really improves outcomes in high-risk patients.

Methods: We included a total of 51 high-risk patients with severe aortic valve stenosis. Patients were allocated to transapical aortic valve implantation (n = 21) or minimally invasive aortic valve replacement via a partial upper sternotomy (n = 30), in a nonrandomized fashion. Patient age, preoperative comorbidities, and perioperative risk, expressed as logistic EuroSCORE (38% ± 14% vs 35% ± 9%), were matched between the 2 groups.

Results: Early morbidity and mortality were comparable between groups, but transapical aortic valve implantation was associated with shorter operative time ($P = .004$), ventilation time ($P < .001$), intensive care unit stay ($P < .001$), and hospital stay ($P < .001$). Thirty-day mortality was 14% (n = 3) in the transcatheter group versus 10% (n = 3) in the surgical group. After a mean follow-up of 12 ± 4 months (100% complete), there were a total of 5 (24%) deaths in the transapical group versus 5 (17%) deaths in the open surgery group. There was 1 intraoperative death in the transapical group versus none in the surgery group. In the transapical group, there were 2 re-explorations for bleeding, 2 intraoperative conversions, 1 case of prosthesis migration, and 2 impairments of coronary arteries. The surgery group included 1 re-exploration, 1 stroke, 1 pacemaker implantation for complete atrioventricular block, and 3 cases of atrial fibrillation.

Conclusions: Current data suggest a faster postoperative recovery after transapical aortic valve implantation, with early and late morbidity and mortality comparable with those of minimally invasive aortic valve replacement via partial upper sternotomy.

Classic surgical aortic valve replacement (AVR) with full sternotomy and cardiopulmonary bypass (CPB) has been performed for decades and is the established gold standard in the treatment of severe, symptomatic aortic valve stenosis. This procedure has been demonstrated to have excellent functional outcomes with satisfactory long-term survivals even in patients aged 80 years and older.[1-6] Despite all efforts, mortality after routine AVR may be as high as 20% in patients with significant comorbidities, including left ventricular dysfunction,[7] and some have been considered nonsurgical candidates. Thus, there is an ongoing attempt to evaluate and to define alternative, less invasive treatment options for these highest risk patients.

The past decade has brought considerable progress in the development of less invasive approaches to heart valve surgery. Consequently, a variety of partial sternotomies has been developed to provide access to the aortic valve with excellent rib cage stability, improved postoperative breathing mechanics, and reduced pain.[8-12] At our center we moved from a reversed L-shaped partial upper sternotomy (PUS) into the fourth or fifth right intercostal space to an L-shaped PUS into the fourth or fifth left intercostal space.[13] This approach became our routine access for aortic valve surgery. Despite excellent results, the use of CPB, aortic crossclamping, and cardioplegic arrest are still required.

Most recently, intense interest has been focused toward the development of a percutaneous catheter–delivered valve for use in patients with critical aortic stenosis for whom surgical therapy has been rejected.[13,14] Selected centers including our institution have started to perform the alternative transapical aortic valve implantation (TAP–AVI) in highest risk patients with severe symptomatic aortic valve stenosis.[15-19] Initial results are encouraging, but to date there are no data available comparing this evolving approach with an established minimally invasive concept for AVR. Thus the purpose of the current investigation was to compare the initial 21 patients who underwent TAP–AVI at our center with a matched cohort of 30 patients with minimally invasive AVR via PUS (PUS–AVR).

PATIENTS AND METHODS

The study was approved by the Institutional Review Board of the Hospital of the Johann Wolfgang Goethe University Frankfurt/Main, Germany,

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Abbreviations and Acronyms

AVI = aortic valve implantation
AVR = aortic valve replacement
CPB = cardiopulmonary bypass
PUS = partial upper sternotomy
PUS–AVR = minimally invasive aortic valve replacement via partial upper sternotomy
TAP–AVI = transapical aortic valve implantation (implant)

and informed consent and permission for the release of information were obtained from each patient. For the purpose of this investigation, we first reviewed our computerized database of the initial 21 patients who underwent TAP–AVI between January 2006 and April 2007. We then matched these 21 patients 1:1 with patients who underwent L-shaped PUS–AVR with respect to preoperative variables that are known to affect perioperative and postoperative outcomes after AVR (Table 1). The resulting 30 PUS–AVR patients were operated on in 2006 for isolated aortic valve stenosis and represented the 16% of the total PUS–AVR patients from this time interval with the highest perioperative risk. Patients included in this study typically qualified for either approach, and the final decision was mainly based on the patient's preference. For operative survivors, mean late follow-up for reoperation or death was 12 ± 4 months and was 100% complete. Induction of anesthesia was performed in a standard fashion in both groups. Propofol infusion was used to maintain anesthesia during postoperative ventilation to promote early extubation. The current study represents an intent-to-treat analysis.

TAP–AVI

High-risk patients with severe symptomatic aortic stenosis and an aortic valve orifice area of 0.8 cm^2 or less were selected for TAP–AVI. High risk was defined by a logistic EuroSCORE predicted risk for mortality of greater than 20%.[18] Additional inclusion criteria for TAP–AVI were an age of 75 years or more, echocardiographically measured aortic annulus diameter of 24 mm or less, as well as symmetrically distributed calcification of the stenotic native aortic valve cusps. All operations were performed in a specially equipped angiography suite that fulfills the standards of a hybrid operating room. The Cribier–Edwards prosthesis (Cribier–Edwards; Edwards Lifesciences, Irvine, Calif), which is a pericardial xenograft mounted on a stainless steel stent available in two sizes (23 and 26 mm), was used.[15,18,20,21] Patients were placed in a supine position. The femoral vessels were exposed, either for cannulation for CPB or to place a venous and an arterial guidewire (off-pump procedure) for safety reasons to be prepared for fast cannulation. Technical details of TAP–AVI have been previously described in detail.[15,18,19] In brief, a limited anterolateral incision (5–7 cm), in the fifth intercostal space, was used to access the apex of the heart. A bipolar epicardial pacing wire was placed and tested. Two U-shaped stitches with Teflon felt pledgets using 3-0 Prolene polypropylene (Ethicon, Inc, Somerville, NJ) were placed in the apex of the left ventricle. They served as a purse string for linear closure of the left ventricle at the end of the procedure. Fluoroscopy and transesophageal echocardiography were used to guide the catheter across the native valve and to direct deployment of the stent at the level of the annulus. During valve deployment, the heart was unloaded with CPB or with rapid ventricular pacing. Valve function was immediately assessed by angiographic and echocardiographic visualization. The transapical sheath was removed and the apex securely closed with the purse-string sutures. CPB was weaned (n = 11), if necessary, and all cannulas removed. The pericardium was partially closed over the apex and a left lateral chest tube was inserted. The incision was closed in a standard fashion. Patient demographics are summarized in Table 1.

L-Shaped PUS–AVR

The procedure was performed in a routine operating room. Patients were placed in a supine position. A limited median skin incision (7–9 cm) was made from just beneath the sternal angle to the fourth intercostal space. The soft tissue was dissected and a flap was raised to allow access to the sternal notch. The sternum was opened from the sternal angle to the fourth or fifth intercostal space. The sternal incision was ''L'd'' into the left fourth or fifth intercostal space. Care was taken not to damage the left internal thoracic artery. Cannulas for CPB were placed directly into the ascending aorta and right atrium after the pericardium was opened; the cannulas were tacked to the drapes under tension with stay sutures. In our experience, this maneuver elevated the heart anteriorly and afforded good exposure of the aorta and right atrium. The field was flooded with carbon dioxide at 2 L/min to aid resorption of gas bubbles from the bloodstream. Cardioplegic solution was delivered only antegradely through an aortic root cannula and after aortotomy by selective coronary intubation. All subsequent steps of the procedure equaled those of routine AVR. Perimount–Edwards stented bioprostheses (Edwards Lifesciences) with a mean size of 22.7 ± 1.6 mm were used in all patients.

Statistical Evaluation

Categorical variables are expressed as percentages and continuous variables are expressed as mean ± standard deviation. All statistical analyses were performed with SigmaStat 2.03 software (SPSS, Inc, Chicago, Ill). Comparison of categorical variables was performed with $\chi 2$ or Fisher's exact tests, and continuous variables were analyzed with unpaired *t* tests or Wilcoxon tests.

RESULTS

Operative Outcomes

In the TAP–AVI group, all valves were successfully deployed at the target. In 1 patient valve embolization into the aortic arch occurred during a second inflation of the balloon owing to a severe paravalvular leakage. On control echocardiography, all other valves showed good hemodynamic function. Repeat valve dilatation was performed because of uneven stent expansion leading to moderate or severe paravalvular leak in 5 (24%) patients. Three (14%) patients retained mild (first-degree) aortic insufficiency owing to paravalvular leakages. In 2 patients, conversion to open surgery was necessary, once in the patient with valve embolization and again in a patient with a porcelain aorta in whom a type A dissection developed after balloon dilatation. Two patients in the transapical group required stent angioplasty inasmuch as the left main stem was partially obstructed by the native valve. In the PUS–AVR group, all valves showed good hemodynamic function without relevant paravalvular leakage. None of the patients required conversion to full sternotomy.

Operative time accounted for 154 ± 33 minutes in the TAP–AVI group versus 208 ± 28 minutes ($P = .004$) in the PUS–AVR group. In 15 (71%) patients, TAP–AVI was performed after cannulation of the femoral vessels. Nine (43%) of them were actually supported with the pump for 11 ± 3 minutes to unload the heart during valve deployment. Two other patients were supported with the

TABLE 1. Demographic characteristics of study population

	TAP–AVI	PUS–AVR	*P* value
No. of patients	21	30	NA
Age (y)	85 ± 6	82 ± 4	NS
Male gender	6 (29%)	11 (37%)	NS
Ejection fraction < 30%	5 (24%)	6 (20%)	NS
Respiratory dysfunction/COPD*	7 (33%)	10 (33%)	NS
Diabetes mellitus	6 (29%)	7 (23%)	NS
Renal insufficiency	4 (19%)	3 (10%)	NS
Coronary artery disease†	9 (43%)	11 (37%)	NS
Presence of mitral incompetence ≤ second degree‡	4 (19%)	6 (20%)	NS
Peripheral vascular disease	4 (19%)	7 (23%)	NS
Porcelain aorta	3 (14%)	0	NS
NYHA class	3.4 ± 0.4	3.2 ± 0.2	NS
Previous cardiac surgery	3 (14%)	0	NS
Previous stroke	3 (14%)	1(5%)	NS
Pulmonary hypertension	6 (29%)	7 (23%)	NS
Arrhythmia	6 (29%)	8 (27%)	NS
EuroSCORE predicted risk for mortality§	38 ± 14 %	35 ± 9 %	NS

n (%) is listed for categorical variables; mean ± 1 standard deviation for normally distributed continuous variables. *TAP–AVI,* Transapical aortic valve implantation; *PUS–AVR,* minimally invasive aortic valve replacement via partial upper sternotomy; *COPD,* chronic obstructive pulmonary disease; *NYHA,* New York Heart Association; *NS,* not significant. *Forced expiratory volume in the first second < 1 L; †diffuse coronary artery disease without any indication for surgical treatment or status-post percutaneous transluminal coronary angioplasty; ‡no indication for concomitant surgical valve repair; §according to logistic EuroSCORE calculations.

pump for 78 ± 7 minutes after conversion to median sternotomy. In these 2 patients, crossclamp time was 58 ± 4 minutes. The last 10 patients received off-pump TAP–AVI with only a femoral venous and arterial wire in place. CPB and aortic crossclamp times in the PUS–AVR group accounted for 113 ± 15 and 71 ± 7 minutes, respectively. Operative outcomes are summarized in Table 2.

Hospital Course

TAP–AVI was associated with shorter ventilation time ($P < .1$), intensive care unit stay ($P < .001$), and hospital stay ($P < .001$) than PUS–AVR (Table 3). Two (10%) patients underwent re-exploration for bleeding versus 1 (3%) in the surgical group. In the PUS–AVR group, there was 1 (3%) stroke, 1 (3%) pacemaker implantation for complete atrioventricular block, 3 (10%) cases of atrial fibrillation, and 3 (10%) cases necessitating postoperative hemodialysis. None of these morbidities was encountered in TAP–AVI patients.

Thirty-day mortality was 14% (n = 3) in the transcatheter group (TAP–AVI), including the 1 intraoperative death resulting from dissection of the aortic root. There were another 2 deaths in patients with multisystem organ failure on postoperative days 3 and 5. The postoperative course in these 2 patients was complicated by leg ischemia after cannulation of the femoral vessels in 1 patient and development of a Leriche syndrome in the second patient. Postmortem

TABLE 2. Operative outcomes with TAP–AVI or PUS–AVR

	TAP–AVI (n = 21)	PUS–AVR (n = 30)	*P* value
Operative time (min)	154 ± 33	208 ± 28	.004
CPB time (min)	*	113 ± 15	NA
Crossclamp time (min)	†	71 ± 7	NA
Type A dissection	1 (5%)	0	NS
Prosthesis migration	1 (5%)	0	NS
Coronary obstruction	2 (10%)	0	NS
Conversion to median sternotomy	2 (10%)	0	NS
Intraoperative death	1 (5%)	0	NS

n (%) is listed for categorical variables; mean ± 1 standard deviation for normally distributed continuous variables. *TAP–AVI,* Transapical aortic valve implantation; *PUS–AVR,* minimally invasive aortic valve replacement via partial upper sternotomy; CPB, cardiopulmonary bypass; *NA,* not applicable; *NS,* not significant. *Nine patients were taken on pump via femoro–femoral cannulation for 11 ± 3 minutes to unload the heart during valve deployment; 2 patients were taken on pump for 78 ± 7 minutes after conversion to median sternotomy; †crossclamp time was 58 ± 4 minutes for the 2 patients with conversion to median sternotomy.

assessment in both patients confirmed good prosthetic valve position and function, as well as patent coronary ostia. In the PUS–AVR group, 30-day mortality was 10% (n = 3). One patient died of multisystem organ failure in low-output syndrome on postoperative day 4, another died of left ventricular failure on postoperative day 6, and the third patient died of pneumonia after a prolonged stay in the intensive care unit on postoperative day 21.

One-Year Follow-up

After a mean follow-up of 12 ± 4 months, there were a total of 5 (24%) deaths in the transapical (TAP–AVI) group versus 5 (17%) deaths (17%) in the surgery (PUS–AVR) group (Table 4). In the TAP–AVI group, severe pulmonary arterial hypertension refractory to maximum medical therapy led to right heart failure with subsequent death 6 months postoperatively in 1 patient; the other late death was caused by pneumonia 8 months after intervention. Similarly, there were 2 late deaths during follow-up in the surgical group,

TABLE 3. Hospital course after TAP–AVI or PUS–AVR

	TAP–AVI (n = 21)	PUS–AVR (n = 30)	*P* value
Ventilation time (h)	6 ± 2	18 ± 3	<.001
ICU stay (d)	1.0 ± 0.4	3.2 ± 1.9	<.001
Hospital stay (d)	5.0 ± 0.9	12 ± 3.4	<.001
Re-exploration	2 (10%)	1 (3%)	NS
Complete atrioventricular block	0	1 (3%)	NS
Pacemaker implantation	0	1 (3%)	NS
Stroke	0	1 (3%)	NS
Atrial fibrillation	0	3 (10%)	NS
Dialysis	0	3 (10%)	NS
Thirty-day mortality	3 (14%)	3 (10%)	NS

n (%) is listed for categorical variables; mean ± 1 standard deviation for normally distributed continuous variables. *TAP–AVI,* Transapical aortic valve implantation; *PUS–AVR,* minimally invasive aortic valve replacement via partial upper sternotomy; *ICU,* intensive care unit; *NS,* not significant.

TABLE 4. One year's follow-up after TAP–AVI or PUS–AVR

	TAP–AVI (n = 21)	PUS–AVR (n = 30)	*P* value
Aortic valve orifice area (cm^2)	1.5 ± 0.8	1.7 ± 0.5	NS
Mean transaortic valve gradient (mm Hg)	9.6 ± 3.7	7.3 ± 3.7	NS
Endocarditis	0	1 (3%)	NS
Reoperation	1 (5%)	1 (3%)	NS
Overall mortality at 1 year's follow-up	5 (24%)	5 (17%)	NS

n (%) is listed for categorical variables. *TAP–AVI,* Transapical aortic valve implantation; *PUS–AVR,* minimally invasive aortic valve replacement via partial upper sternotomy; *NS,* not significant.

including 1 case of left ventricular failure 7 months postoperatively and 1 case of sudden death owing to a ruptured abdominal aortic aneurysm 11 months after the operation. There was 1 reoperation in each group.

DISCUSSION

With the recent onset of TAP–AVI in selected centers including our institution, the invasiveness of surgical intervention for aortic stenosis has been further reduced by eliminating the need for CPB, aortic crossclamping, and cardioplegic arrest, allowing for a true off-pump procedure without sternotomy.[17-19] Thus TAP–AVIs currently draw their justification for use from a potential reduction of perioperative risk, which intuitively makes sense. However, to date no data are available comparing this evolving approach with an established minimally invasive surgical procedure for AVR. Therefore, it remains unclear whether TAP–AVI really improves outcomes in high-risk patients.

In comparing operative morbidity in the present study, we have to keep in mind that TAP–AVI is an emerging approach with limited worldwide experience. Despite the fact that all valves were successfully deployed at the target, we faced some initial technical difficulties early in the series. Owing to the natural learning curve associated with a new approach, there were two conversions to open surgery with one causing the only intraoperative death within this series, and 2 patients required stent angioplasty inasmuch as the left main stem was partially obstructed by the native valve. This may seem a potential disadvantage when compared with the operative outcomes with PUS–AVR. However, widely feared complications after AVR such as stroke, complete atrioventricular block, and postoperative arrhythmias occurred at a low incidence within the PUS–AVR group, but were absent after TAP–AVI. At the same time, current data support the assumption that reduction of surgical trauma should lead to a faster postoperative recovery after TAP–AVI because ventilation time, intensive care unit stay, and hospital stay were significantly reduced ($P < .0001$ vs PUS–AVR). Surprisingly, despite the high incidence of renal insufficiency within this series, the additional burden of 78 ± 41 mL contrast given during the procedure did not necessitate postoperative hemodialysis in the TAP–AVI group. In contrast, the negative impact of CPB on postoperative renal function was well accepted,[22] and 10% of patients actually required postoperative dialysis after PUS–AVR.

Thirty-day mortality was comparable between the groups, with 14% in the transapical group and 10% in the surgical group. Preoperative comorbidities such as peripheral vascular disease or concomitant coronary artery disease with reduced left ventricular function complicated the postoperative course and eventually contributed to early mortality. According to these preliminary data, there is no survival advantage with TAP–AVI. On the other hand, one may argue that an evolving surgical concept is initially judged by the ability to keep up with the established approach without compromising survival. Also, with gained experience in the later half of the TAP–AVI series, we observed a steep learning curve, particularly with regard to the hemodynamic management before valve deployment. None of the last 10 patients without femoro–femoral cannulation required secondary conversion to an on-pump procedure. Severe hypotension and subsequent subendocardial ischemia were reliably avoided by raising systolic blood pressure to 120 to 140 mm Hg with low-dose norepinephrine before rapid ventricular pacing during valve deployment. Obviously, 30-day mortality in both groups was far below the predicted perioperative risk of mortality according to logistic EuroSCORE calculations. Such an observation raises the question of the reliability of such a risk stratification model.

In patients undergoing heart valve procedures, the EuroSCORE model has been shown to be predictive of early mortality,[23] postoperative complications,[24] prolonged length of stay,[24] and long-term mortality.[25] The use of the EuroSCORE in predicting operative mortality for high-risk patients undergoing isolated AVR has yet to be validated. Although the logistic EuroSCORE model has been shown to be a better predictor of mortality than the additive EuroSCORE in high-risk populations,[26,27] several studies have found that the logistic EuroSCORE model may overestimate the mortality of such patients undergoing valve procedures.[28,29] This is particularly true for patients aged 80 years and older.[30] In contrast, the logistic EuroSCORE may underestimate the actual risk of mortality in patients younger than 80 years. The reason is that various preoperative comorbidities, including coronary artery disease, mitral valve incompetence, hepatic disease, malignancies, cardiovascular risk factors (smoking history, hypertension), presence of a porcelain aorta, or radiation of the chest, are not necessarily reflected.[18] In fact, we also believe that in the absence of a uniformly accepted and validated risk stratification model, we had to use the EuroSCORE estimate to comply with data presented in recent clinical series.[18,19]

At 1 year's follow-up, the comparable early morbidity and mortality between TAP–AVI and PUS–AVR were

confirmed with a total of 5 deaths in each group, accounting for a 24% mortality rate in the transapical approach versus 17% in the open surgery group.

Potential Limitation

Although our study was not randomized, we matched patients according to variables known to affect morbidity and mortality after AVR. Regarding the comparability between the 2 groups, it also seems important to mention that 6 patients from the surgical group were initially considered for TAP–AVI, but eventually underwent PUS–AVR because of an aortic annulus diameter larger than 25 mm. Another limitation of our study is its retrospective nature. The study was not a randomized trial, and some of the observed differences may thus be attributable to bias or unmeasured factors. Furthermore, we are comparing a new procedure with an established approach. Although this may underestimate the true benefits of TAP–AVI once the initial learning curve has been overcome, we believe that we have to share our early experiences with other centers that are beginning to pursuit this evolving approach worldwide. This way, surgeons will know what clinical results and problems they may initially face with TAP–AVI as compared with their established practice of AVR. Besides, even with growing international experience, the initial learning curve of an individual center cannot be completely eliminated.

In summary, current data suggest a faster postoperative recovery after TAP–AVI with early and late morbidity and mortality comparable with those of PUS–AVR.

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Discussion

Dr Eric Roselli *(Cleveland, Ohio)*. I am also a co-investigator for the percutaneous valve trial.

Congratulations on a commendable early experience with this new transapical technology. For now, I believe the real advantage of this approach is that it offers the ability to provide nonoperative candidates a viable treatment option for symptomatic and fatal disease. Although the EuroSCOREs were similar, this scoring system, like others, has been criticized for the inability to capture less

quantifiable factors that make a patient high risk. Furthermore, you could not have matched patients for technical expertise during that initial learning curve phase, although you did a nice job of addressing that point. Were any of these 21 patients deemed to be in inoperable condition and therefore part of a different population from the matched cohort, and were any symptomatic patients with severe aortic stenosis treated medically during this time period? If so, how did they do?

Dr Doss. Thank you very much for your comments. Of course, matching these patients is difficult. As you have pointed out, the transapical group included patients who were in somewhat inoperable condition. We had patients with porcelain aortas and we had redo patients, which we did not have in the surgical group. Therefore, this was a very sick and very challenging operative group of patients.

Dr Roselli. Did you evaluate any medically treated patients during this time period?

Dr Doss. No, we did not have a medical treatment arm. We did have patients who were on the waiting list and died while waiting for surgery, but we did not have a specific medical arm for these patients.

Dr Roselli. I believe that this technology will become another important tool in our armamentarium, especially for high-risk patients, but I worry that the attraction of this less invasive approach may cloud our judgment in providing patients with a durable operation, especially if the delivery systems improve access and accuracy in deployment. You had 5 patients, I believe, who required repeat balloon valvuloplasty and 1 patient in each of the 2 groups who required late reoperation. Can you provide any further follow?up data on echocardiographic evidence of aortic insufficiency and describe how you monitored these patients afterward?

Dr Doss. As I said before, 4 patients had paravalvular leakages; the leakages were not significant. We followed them up according to the protocol, which was after 30 days, after 6 months, and after 1 year, and thereafter we monitored them yearly. Of those patients who had paravalvular leakages, none of the patients actually went on to have a hemolysis, and none of the patients required a reoperation for hemodynamic compromise. Also, none of these incompetencies increased the grading. Therefore, it was something that we also had to learn—that leaving paravalvular leakages that are not significant can actually be tolerated by the patient. A surgeon would try to reoperate on these patients as soon as possible, but in these procedures, these patients tended to do well even though these paravalvular leakages were not treated.

Dr Lars Svensson *(Cleveland, Ohio).* It is interesting to see how the group of high-risk patients has increased in Europe, and that certainly has been our impression with our patients. We looked at our first 92 patients who were referred for percutaneous valves: essentially 20% underwent open surgery with no deaths, 20% received percutaneous valves and did pretty well, and 20% just had balloon valvuloplasty; another 40% died before the procedure, refused, or were not suitable for any type of procedure.

Are you doing a lot of balloon valvuloplasty bridging for later procedures?

Dr Doss. Actually, we did that in only 2 patients. Those were patients with very bad left ventricular function, less than 20%. Bridging was done in an attempt to let them improve and then be available for a later transapical procedure.

Dr William Northrup III *(Kennesaw, Ga).* I have one simple question in the context of Craig Miller's provocative presidential address. How many of your patients eventually ended up going back to their own ZIP codes?

Dr Doss. I did not quite get the phrase.

Dr Svensson. How many of those patients went back to normal reasonable lifestyles in their home village?

Dr Doss. The big advantage of the transapical procedure is that if you treat these very sick patients, you actually see that they do have a much improved and better course in the hospital. The second patient on whom we performed the transapical procedure was a 92-year-old man with coronary artery disease. We stented his coronary arteries, 1 month later we did the procedure, and the patient returned to the hospital with his wife 1 year later. He was living at home and taking care of himself. Of course, he will not live another 10 years, but the improvement in his quality of life was dramatic. It is dramatic with this type of procedure. The transapical procedure is worth doing, not necessarily to improve their survival, but definitely to improve their quality of life during the time that they have left.